

## What are electronic cigarettes or e-cigarettes?

Electronic cigarettes, also known as e-cigarettes, are typically battery-operated products designed to deliver a heated solution, or vapor, of nicotine and other chemicals to the user. E-cigarettes can be disposable or consist of a rechargeable battery-operated heating element; a replaceable or refillable cartridge that may contain nicotine, flavoring agents, and other chemicals (sometimes called “e-juices”); and an atomizer that uses heat to convert the contents of the cartridge into a vapor that is inhaled by the user.<sup>i</sup> Some e-cigarettes are designed to look like cigarettes, cigars, pipes, or hookahs.

### This factsheet will review:

- What is an e-cigarette
- Are they safe
- Is nicotine safe
- Use (initiation & quitting)
- Marketing
- Regulation
- Where ACS CAN stands

## Are e-cigarettes safe, as manufacturers claim?

There are more than 250 types of e-cigarettes on the market today and the products vary considerably by ingredients, quality control and assurance, and ability to reliably deliver nicotine to users. E-cigarette manufacturers claim the ingredients are “safe,” but without federal regulation, there is no sure way for e-cigarette users to know what they are consuming and the extent of potential risk.

Currently, only a limited number of studies have examined the contents of e-cigarette vapor. Some of the studies have found the vapor to contain only propylene glycol, nicotine, and flavorings, and other studies found them to contain heavy metals, volatile organic compounds and tobacco-specific nitrosamines, among other ingredients. A 2009 study done by the FDA found cancer-causing substances in several of the e-cigarette samples tested.<sup>ii</sup> Additionally, Food and Drug Administration (FDA) tests found nicotine in some e-cigarettes that claimed to contain no nicotine. Propylene glycol is used for food preservation among other uses, and while generally recognized as safe by the FDA for those uses, there is no evidence to date on the safety of inhaling propylene glycol in e-cigarettes, especially in a heated solution and over a long period of time.

The health effects of e-cigarettes are scientifically uncertain, especially their long-term effects. There is general agreement among scientists in the field that, in the short run, at least, e-cigarettes are almost certainly less harmful than combusted cigarettes. But there are still serious questions about the safety of inhaling the substances in some e-cigarette vapor. E-cigarettes have not been subject to thorough, independent testing, so users cannot be sure of what they are actually inhaling. Some studies have shown that some e-cigarettes can cause short-term lung changes and irritations and the long-term health effects, as noted above, are unknown.

Additionally, the effects of secondhand vapor from e-cigarettes require further study, especially to determine differences among the many brands and types of e-cigarettes. Finally, the health impact on individuals using e-cigarettes while also using other tobacco products, such as cigarettes, is not documented in the scientific literature. This is a particularly important area of study because initial reports

of e-cigarette use indicate that e-cigarettes are used by some cigarette smokers in addition to smoking cigarettes, rather than as a replacement for cigarettes. More research is needed to determine if continuing to smoke cigarettes, even fewer, along with e-cigarette use poses a risk for premature death and disease.

### **Is the nicotine used in e-cigarettes safe?**

Nicotine is a drug found naturally in tobacco. Its dependence-producing properties are similar to those of heroin or cocaine.<sup>iii</sup> The risk for addiction depends on the dose of nicotine delivered, the way it is delivered, and the length of time over which it is used. Nicotine addiction can cause withdrawal symptoms when an individual tries to quit. Several nicotine replacement therapies – such as gum, patches, sprays, inhalers, or lozenges – have been approved by the FDA as safe and effective for use to help relieve withdrawal symptoms, without providing the cancer-causing chemicals found in tobacco products. However, exposure to nicotine can still have harmful consequences for some users. Scientific evidence has shown that nicotine affects maternal and fetal health during pregnancy, potentially leading to preterm delivery or stillbirth and adverse consequences to brain development of the fetus.<sup>iv</sup> Additionally, scientific evidence suggests that nicotine can have long-term adverse effects on brain development among adolescents. Therefore, pregnant women and adolescents are cautioned from using any nicotine containing products, including e-cigarettes.

### **Who is using e-cigarettes, and how are they used?**

There is very little surveillance of e-cigarette use in the United States to date. A study from the Centers for Disease Control and Prevention (CDC) found that e-cigarette experimentation increased among middle and high school students between 2011 and 2012 (from 3.3 percent to 6.8 percent), resulting in an estimated 1.78 million youth who have tried e-cigarettes.<sup>v</sup> Current e-cigarette use increased for this population of youth from 1.1 percent to 2.1 percent. These increases were greater among high school students.

A study of 2010-11 data found the number of adults who have ever used e-cigarettes increased from 3.3 percent to 6.2 percent.<sup>vi</sup> In 2011, 21.2 percent of current smokers had ever tried e-cigarettes, as compared to 7.4 percent of former smokers and 1.3 percent of never smokers, suggesting that, at the present, e-cigarette use among adults is largely confined to current and former cigarette smokers. Another study found that the majority of e-cigarette users across four countries reported using e-cigarettes to help them quit cigarettes and because they thought they were less harmful than cigarettes.<sup>vii</sup>

### **Will e-cigarettes help people stop using tobacco products entirely?**

There have been only a few randomized controlled trials of e-cigarettes as a smoking cessation aid.<sup>viii</sup> Only one of these compared the effectiveness of e-cigarettes as a quitting aid to an already- tested, approved quitting medication. The study compared the use of nicotine-replacement therapy patches and e-cigarettes with the outcome of abstinence from cigarettes at 6 months. It concluded that e-cigarettes may be at least as effective as nicotine patches aiding in quitting cigarettes (7.3 percent and 5.8 percent 6 months abstinence, respectively). Other studies that have attempted to look at the potential of e-cigarettes as a cessation aid have found that, while e-cigarettes may aid in reducing the number of

cigarettes smoked, there was not a significant difference between smokers who used e-cigarettes and smokers who did not use e-cigarettes in terms of quitting cigarette use entirely.<sup>ix</sup>

Therefore the question still remains whether, and to what degree, e-cigarettes are an effective smoking cessation aid, and whether reducing the number of cigarettes smoked by using both e-cigarettes and cigarettes at the same time reduces an individual's risk for premature death and disease. The answers to these questions and others must come from a wide-ranging, independent research agenda.

In the absence of FDA guidance and sufficient research evidence establishing e-cigarettes as an effective method to help smokers quit, **ACS CAN does not at this time recommend e-cigarettes for smoking cessation**. Instead, for those smokers for whom it is appropriate to use a cessation medication, ACS CAN recommends use of one FDA-approved and thoroughly tested smoking cessation medications (i.e. nicotine replacements – gum, patch, lozenge, inhaler, nasal spray - or bupropion or varenicline).

### **Will youth use e-cigarettes as an introduction to regular cigarettes?**

The rapid increase in youth trying e-cigarettes in recent years raises questions as to whether these youth will be drawn into long-term nicotine addiction and whether they will supplement or replace e-cigarette use with cigarettes or other tobacco products. The lack of surveillance of e-cigarette use makes this question hard to answer at this time, but there are several key factors, based on past experience with tobacco industry products and marketing, that raises the concern of some in the public health and health community.

First, more than 80 percent of adult smokers report starting before the age of 18 and adolescents who use smokeless tobacco are more likely to become adult smokers than adolescents who do not use smokeless tobacco.<sup>x</sup> This suggests that nicotine experimentation in youth can lead some youth to a lifetime of nicotine addiction and use of tobacco products. Second, the widespread, unregulated use of e-cigarettes has the potential to result in smoking once again as a socially acceptable behavior which has potentially significant implications for youth initiation and adult continuation of cigarette smoking. Third, e-cigarettes are accessible to youth since they are not covered under all state and local youth access laws and are available for purchase through the internet. Finally, many of the makers of e-cigarettes are utilizing tobacco company product and marketing tactics that have been proven effective at targeting youth, including the use of candy flavoring and celebrity endorsements. The increase in youth trying e-cigarettes is not surprising given the increased access to, promotion of, and exposure to e-cigarettes; and raises serious questions on the potential for long-term nicotine addiction and use of cigarettes and other tobacco products.

### **How are e-cigarettes being marketed?**

E-cigarettes are widely available to nearly anyone who wishes to purchase them, since they are often not subject to the same legal restrictions as cigarettes and other tobacco products. E-cigarettes are advertised on television, radio, online, in print magazines, including those with high youth readership, and at sports and music events. Some e-cigarette manufacturers are using the same marketing practices effectively used by the tobacco companies to target youth and mislead consumers about the potential safety and health impact of their products. Such practices include celebrity endorsements, sports and musical

sponsorships, and images of e-cigarettes as rebellious, sexy and cool, as well as the use of flavorings in their products.<sup>xi</sup> Some e-cigarette manufacturers claim e-cigarettes are a safe, less harmful alternative to cigarettes despite the lack of regulation to ensure their safety or health impact. Additionally, e-cigarettes are advertised as a way to “legally smoke” or “take back your freedom” where smoke-free laws exist in states and localities. As part of its request for FDA to regulate e-cigarettes, several leading members of Congress have developed a side-by-side presentation of e-cigarette and cigarette marketing practices ([democrats.energycommerce.house.gov](http://democrats.energycommerce.house.gov)).

### **Why the controversy?**

The potential benefits of e-cigarettes are the ability to deliver nicotine to the user without many of the other harmful chemicals in cigarettes, the absence of secondhand cigarette smoke, and the potential to aid smokers in quitting cigarettes.

There are concerns, however, that because these products are unregulated and current research provides mixed views of whether the potential benefits will be borne out in the long run, the safety claims made by manufacturers are unsubstantiated by objective scientific evidence and may be misleading the public. FDA regulation of e-cigarettes and sufficient science-based, independent research is essential in order for the public health and health community, cigarette smokers, and the public at-large to be accurately informed about e-cigarettes, including the ingredients and the potential benefits or harms of use. Research is also needed to assess whether youth can be drawn into long-term nicotine use through e-cigarettes, whether wide use of e-cigarettes can re-normalize cigarette use, and whether e-cigarette use will be a net harm or benefit for population-based public health. There is a growing scientific literature surrounding e-cigarettes and considerable research is underway. The controversy surrounding e-cigarettes and harm reduction more broadly will not go away, but as these results become available and FDA asserts its authority to regulate these products, more accurate, science-based policies and public education can be developed.

### **Are e-cigarettes regulated?**

When e-cigarettes were first introduced on the market, the FDA tried to regulate e-cigarettes as a drug-delivery device, like other tobacco cessation aids such as nicotine gum or patches. NJOY, one e-cigarette maker, presented a legal challenge and a federal court ruled e-cigarettes can only be regulated as a drug-delivery device when a therapeutic claim is made (ex. aids in cessation); without such claim, the only way the FDA can assert its regulatory authority over e-cigarettes is to regulate them as tobacco products. Currently, however, e-cigarettes remain unregulated. FDA has stated its intent to assert the authority of the Center for Tobacco Products to regulate all tobacco products, but a rule has yet to be issued. FDA assertion would allow the agency to require e-cigarette manufacturers to register their products with the FDA, provide FDA with their ingredients, establish good manufacturing practices, address impure/untested product additions and misbranding issues, and restrict marketing and sales only to those 18 years and older, among other potential regulations.

### **What are ACS CAN’s views on e-cigarettes?**

**In the absence of FDA guidance and sufficient research evidence establishing e-cigarettes as an effective method to help smokers quit, ACS CAN does not at this time recommend e-cigarettes for smoking**

cessation. Instead, for those smokers for whom it is appropriate to use a cessation medication, ACS CAN recommends use of one or more of the seven FDA-approved and thoroughly tested smoking cessation medications (i.e. nicotine replacements – gum, patch, lozenge, inhaler, nasal spray - or bupropion or varenicline).

ACS CAN agrees there is a need for a wide-ranging, independent research agenda on e-cigarettes, but we recognize that even without sufficient scientific evidence of the safety or health impact of e-cigarettes, inaction on e-cigarettes is not in the best interest of protection of the public's health. Therefore, ACS CAN supports the FDA asserting its authority to regulate e-cigarettes and other tobacco products and the inclusion of e-cigarettes in state and local evidence-based tobacco prevention and control measures, including prohibiting the use of e-cigarettes wherever smoking is prohibited.

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<sup>i</sup> U.S. Food and Drug Administration. E-Cigarettes: Questions and Answers. September 17, 2010. Available online at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm225210.htm>.

<sup>ii</sup> U.S. Food and Drug Administration. Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA. July 22, 2009. Available online at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm>.

<sup>iii</sup> U.S. Department of Health and Human Services. *The Health Consequences of Smoking: Nicotine Addiction. A Report of the Surgeon General*. Atlanta (GA): U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 1988. DHHS Publication No. (CDC) 88-8406.

<sup>iv</sup> U.S. Department of Health and Human Services. *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

<sup>v</sup> Centers for Disease Control and Prevention. Electronic Cigarette Use Among Middle and High School Students – United States – United States, 2011-2012. *MMWR* 2013; 62(35): 729-730.

<sup>vi</sup> King, BA et al. Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011. *Nicotine & Tobacco Research* 2013; 15(9): 1623-1627.

<sup>vii</sup> Adkison S, et al. Electronic nicotine delivery systems: international tobacco control four-country survey. *American Journal of Preventive Medicine*. 2013 March; 44(3): 207-215.

<sup>viii</sup> Bullen C., et al. Electronic cigarettes for smoking cessation: a randomised controlled trial. *The Lancet*, Early Online Publication, 9 September 2013.

<sup>ix</sup> Adkison S, et al. Electronic nicotine delivery systems: international tobacco control four-country survey. *American Journal of Preventive Medicine*. 2013 March; 44(3): 207-215.

<sup>x</sup> U.S. Department of Health and Human Services. *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012.

<sup>xi</sup> U.S. Surgeon General. *Preventing Tobacco Use Among Youth and Young Adults*. Atlanta, GA: Department of Health and Human Services, Centers for Disease Control and Prevention; 2012